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The Future of Partial Nephrectomy

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Abstract

Innovation in recent times has accelerated due to factors such as the globalization of communication; but there are also more barriers/ safeguards in place than ever before as we strive to streamline this process.

From the first planned partial nephrectomy completed in 1887, it took over a century to become recommended practice for small renal tumours. At present, identified areas for improvement/ innovation are 1) to preserve renal parenchyma, 2) to optimise pre-operative eGFR and 3) to reduce global warm ischaemia time. All 3 of these, are statistically significant predictors of post-operative renal function.

Urologists, have a proud history of embracing innovation & have experimented with different clamping techniques of the renal vasculature, image guidance in robotics, renal hypothermia, lasers and new robots under development. The DaVinci model may soon no longer have a monopoly on this market, as it loses its stranglehold with novel technology emerging including added features, such as haptic feedback with reduced costs.

As ever, our predictions of the future may well fall wide of the mark, but in order to progress, one must open the mind to the possibilities that already exist, as evolution of existing technology often appears to be a revolution in hindsight.

1. Introduction

The central objectives of future study and development are to 1) preserve renal parenchyma, 2) optimise pre-operative eGFR and 3) to reduce global warm ischaemia time (WIT). All 3 have shown to be important predictors of post-operative renal function.

1.2 Clamping: variations of a theme

Although clamping controls operative blood loss, facilitates tumour excision and renal reconstruction, it does cause temporary renal ischaemia and the potential for renal injury [1]. Therefore various techniques have been proposed to reduce WIT and improve renal outcomes.

1.2.1 Off-Clamp Partial Nephrectomy

PN without clamping the renal pedicle has been performed. Renal ischaemia is abolished at the expense of increased blood loss and more difficult renorrhaphy. Techniques for controlling bleeding during 'off-clamp' PN have been explored, for example manual compression of the peri-tumoural parenchyma, or using Kauffman clamps but with mixed success [2].

A recent meta-analysis [3] compared the results of 'off' and 'on' clamp techniques. No significant differences were found in operative times, complications rates or length of stay. A trend was seen towards increased positive margins, blood loss and transfusion rates (figure 1) in the off-clamp group, which could be explained by impaired visualization, though this difference did not reach statistical significance.

Figure 1: Meta-analysis of blood transfusion rates [3].

There was a significantly lower reduction in eGFR at mean 8.36 months associated with off-clamp than on-clamp PN (Standard weighted mean difference 0.27, 95% CI 0.14, 0.40, $p < 0.0001$)(figure 2) [3]. It is not clear whether this corresponds to a reduced risk of CKD; some studies show a disappearance of this advantage at 3 months (as long as the WIT is kept to below 30 minutes) [3], whereas others show a reduced risk of new onset CKD when followed up [1, 4].

Figure 2: Meta-analysis of change in eGFR [3].

To conclude, it seems that the bulk of the evidence suggests that the off-clamp technique for PN when compared to on-clamp PN, leads to a reduced risk of acute kidney injury after surgery, but it is unclear whether it protects from long-term renal impairment. The off-clamp cohort may have a trend towards slightly higher estimated blood loss and transfusion rates (although no statistically significant difference), but with similar numbers of positive margins and complication rates [5] highlighting potential for this technique.

1.2.2 Early Unclamping

Early unclamping has been used successfully to reduce the WIT. Clamps are released immediately after placement of the initial central running suture and prior to the placement of subsequent mattress or bolster sutures. When used in LPN, the technique reduces WIT by >50% with improved post-operative renal function up to 90 days post-operatively ($p<0.001$) [6]. However, RPN is normally associated with shorter WIT, and therefore the physiological significance of shortening the WIT further is difficult to establish. Although the method comes at a risk of higher blood loss, it has been demonstrated to have no effect on transfusion rates or haemorrhagic complications even for complex renal tumours, or for tumours being operated on by less experienced surgeons [7]. It has also been hypothesised that early unclamping may lead to reduced rates of post-operative haemorrhage, as arterial bleeds will be easier to identify in perfused kidney [6].

1.3 Fluorescence image-guided robotic surgery

Fluorescence image-guidance in robotic surgery can potentially improve outcomes for partial nephrectomy in two ways. More accurate dissection of the renal tumour will allow greater preservation of renal parenchyma and more selective arterial clamping will reduce unnecessary ischaemia within healthy renal parenchyma.

The technology uses near-infrared fluorescence (NIRF). A fluorescent contrast agent is administered intravenously, which emits light in the near-infrared wavelength (700-850 nm) after activation by a light emitting diode [8]. The light, not visible to the human eye, is recorded using a charge-coupled device camera. The Da Vinci Si Surgical System has integrated this into its robotic systems, where the surgeon can then switch between standard (white) light and fluorescence-enhanced views in real-time [9]. This is named the Firefly© imaging system.

1.3.1 Preventing ischaemia by selective arterial clamping by NIRF, & The Firefly© imaging system

The action of selective arterial clamping to minimise unnecessary ischaemia and reperfusion injury has been shown to help aid the preservation of renal function [10]. The selection process is aided by NIRF, to identify renal vasculature, assess renal perfusion and dictate the arteries that are to be clamped. The technique allows the surgeon to only clamp off arteries supplying areas of the renal parenchyma that supply the tumour and its immediate margin, while maintaining perfusion of unclamped segments [8].

A dye, commonly indocyanine green (ICG), is injected intravenously and can be identified throughout the vascular system in less than 1 minute [11]. It has 4 properties that make it ideal for this purpose; it stays within the vascular compartment after administration, a plasma half-life of 3-5 minutes, is cleared by hepatic metabolism (and therefore not nephrotoxic), and can be detected by the NIRF camera [12]. This dye is also used for the identification of tumour margins since the fluorescence varies between normal tissue, tumour as well as cysts and necrotic fat. Before administering the dye, the major arterial branches should be clamped with micro bulldog clips. Once the dye has been given, each clamp is released individually to identify the areas of perfusion.

This technique shows great promise. Compared to standard arterial clamping, early results showing significantly superior post-operative kidney function at discharge, and a trend towards significance at 3 months [8].

Other methods of selective arterial clamping have been trialed, for example Colour Doppler ultrasonography. However, due to a complex learning curve and the technology being very operator dependent, uptake has been very limited.

The main limitations to NIRF are the high costs of the Firefly system together with limited evidence of longer-term benefit. Given the good long term renal function and very low dialysis rates already achieved following RAPN, Firefly will need to demonstrate a significant clinical benefit to justify the additional cost.

In conclusion, available evidence suggests that RPN with NIRF provides an improvement of the preservation of renal function at discharge, however this effect may diminish with time.

Figure 3 : NIRF imaging with ICG to facilitate selective arterial clamping. (A) & (B): Dissection of the secondary, tertiary, or quaternary level arterial branches using mini-bulldog clamps. (C) & (D): Renal tumour seen under white light & NIRF, with the hypo-fluorescent renal tumour confirming ischemia with perfused bright green normal renal parenchyma [13].

1.3.2 Using Firefly© to identify renal tumour margins

NIRF has the capability to aid in the identification of tumours and normal tissue. This improved accuracy may not only enable improved dissection and consequently better preservation of healthy parenchyma, but may also enable faster dissection helping to reduce WIT.

Given that the positive margin rate in RPN is already extremely low, it is difficult for a study investigating NIRF to have adequate power to show a difference in positive margin rate. Thus, current studies do not show that NIRF decreases positive margin rate or Clavien III-IV complications [14].

Figure 4: (a) white-light image of a renal tumour. (b) corresponding NIRF image of the same renal tumour. The tumour shows no fluorescent properties.
Photo credits: Advances in Image-Guided Urologic Surgery. Edited by Joseph C. Liao, Li-Ming Su. Springer, 18 Nov 2014.

1.4 Image-Guided Surgery

Image-guided surgery (IGS) allows the integration of pre-operative imaging to allow the surgeon to see beneath the veil of the skin. For partial nephrectomy in particular this will aid firstly the vascular dissection of the kidney and also dissection of the tumour itself.

Two types of IGS are currently available. One uses active intraoperative imaging with various modalities including CT and MRI. Although intraoperative CT and MRI imaging are used in orthopaedics and neurosurgery, their use in urology is likely to be limited. Currently the cost of intraoperative scanners remains prohibitively high and although portable scanners are becoming cheaper, the lack of soft-tissue discrimination for the kidney and suboptimal spatial accuracy restricts their use [15].

The second type incorporates pre-operative images into the visual display of the surgeon. Preoperative 3D images are transformed and mapped to the 3D patient anatomy, a process known as registration [16]. A mesh overlay system allows the surgeon to see the underlying anatomy without visual impedance [17]. A recent study by the University of Florida College of Medicine and Johns Hopkins University demonstrated a technique to increase surgical confidence in excision.

Figure 5: Flowchart of steps for 'registration' of pre-operative CT images to live stereoscopic video [17].

TilePro™ software allows multi-input displays from two data sources to be shown simultaneously with the surgical field at the console. This software starts with a CT scan, which is then used to create a 3-D reconstruction of the organ. These images can then be available to the surgeon on an iPad attached to the DaVinci console which the surgeon can manipulate. This can form an important part of pre-operative planning allowing mental rehearsal of the operation [18].

Figure 6: The console view with TilePro enabled. (A) shows the hilar anatomy with more clarity so better appreciate the anatomy in the operative view. (B) shows the surface of the kidney as a polygon mesh while keeping the tumour solid to aid dissection [18].

However the system is limited by variations in the kidney's anatomy intraoperatively [19]. A technique devised by Su et al [17] allows room for human error during the procedure while aligning the 3D-CT image to the live video footage. Automated segmentation software to obtain precise segmentation is under development. There have also been concerns raised regarding the safety of image-overlay, with surgeons more likely to exhibit inattention blindness [20].

1.5 Renal Hypothermia

Tissue hypothermia has been found to reduce ischaemic damage in different organs, including the kidney. Renal hypothermia has the benefit of allowing for longer clamp times [21] (up to 3 hours without permanent loss of function) [22] by reducing renal metabolism and reperfusion injury after arterial clamping. Reduced renal ischaemic injury further prevents the release of inflammatory and vasoactive peptides that cause tissue damage. There have been many techniques described to induce renal cooling including peri-renal ice slush, cold saline surface irrigation, endoscopic retrograde renal cooling, and trans-arterial renal hypothermia, with varying degrees of success.

Kaouk et al, described intracorporeal cooling which placement of the kidney inside an Endocatch II bag filled with ice slush to achieve a temperature of 5-19 degrees [23]. A recent method that avoids the use of a cumbersome bag, and is not limited to the retroperitoneal approach was by placing ice on the psoas muscle and then over the renal parenchyma, with a laparoscopic sponge placed on the small bowel to prevent bowel cooling ([23]. By utilising a GelPoint trocar the authors could pack and deliver ice around the kidney [24]. The disadvantage to this method is that the ice slush can obscure the operative field. Kaouk et al, describe accidental incomplete clamping of the renal hilum because of missed small arterial branches [23].

1.6 Laser Technology

Various lasers have been used for dissection due to their haemostatic properties. Neodymium-doped yttrium aluminium garnet (Nd:YAG) and yttrium aluminium garnet lasers (Ho:YAG) suffer problems from excessively deep cutting, and smoke formation. The most promising work has been undertaken using diode and thulium lasers. Thulium lasers have excellent cutting and coagulation properties, and emit in a continuous manner [25]. Issues with smoke formation and tissue carbonisation can be controlled with liberal irrigation [26].

1.7 Developments in Robotic Technology

The Da Vinci Xi robot is the latest release from Intuitive Surgical® and offers several advantages to the original model such as the integration of the Firefly system.

Potential future developments include the introduction of haptic feedback and visual force. A trial of visual cues for applied force demonstrated its feasibility in cardiovascular surgery, which reduced the risk of breaking sutures [27].

Other robotic systems are currently in development. The Surgeon's Operating Force-feedback Interface Eindhoven (SOFIE) robot designed by the Eindhoven University of Technology incorporates force feedback. The ability to receive tactile feedback when operating is seen as one of the key senses to enhance accurate movements against resistance. Another advantage is that the robot costs considerably less than the Da Vinci robots. However as yet, these robots have not been commercially priced. It is also much smaller than the Da Vinci system. The slave portion of the robot can be clamped to the surgical bed itself and does not require a bulky robotic arm installation positioned next to the patient (Figure 7). There is no need to reposition the robot as it moves harmoniously with the patient and multiple procedures can take place simultaneously.

Photo credit: Eindhoven University of Technology.
Figure 7: The portable SOFIE robot attached to the patient bed (https://www.tue.nl/en/university/news-and-press/news/27-09-2010-better-surgery-with-new-surgical-robot-with-force-feedback/).

The Raven robot from the University of Washington also comes at a fraction of the cost of the Da Vinci robot. Funded by the US Department of Defense it is intended for use in remote areas. It has 2 arms, and has been tested in extreme environments to show its sturdiness. The mobility of the device offers unrivalled potential as a transportable device.

Virtual fixtures or barriers have been created by Microsoft's Kinect video technology (Microsoft Inc, Redmond, Wash), whereby haptic tele-manipulators cause the surgeon to 'feel' the robotic instrument hitting a virtual barrier set by the surgeon [28]. This would help preserve oncological margins or vital structures.

Photo credit: http://citris-uc.org/telehealth/project/raven-surgical-robotic-system/
Figure 8: The US Department of Defense funded Raven robot – designed for use in remote areas

Another robot under development that has included tactile feedback for the operator is Titan Medical Incorporated's Amadeus surgical system. With a similar master slave design, this system will incorporate ultrasound imaging into its hardware. It will use less rigid instrument shafts made from lighter-weight carbon fillers improving maneuverability and offer better vision with advanced 3D imaging.

Photo credit: http://medcitynews.com/wp-content/uploads/Titan-Medicals-Amadeus.jpg
Figure 9: Titan Medical Incorporated's Amadeus robot, which allows for intra-operative ultrasound imaging

Perhaps most importantly these new robots will bring greater competition. Alongside expiry of current Intuitive patents, it is hoped that prices will be soon be driven downwards [29].

1.8 Conclusions

The future of robotics lies in integrated imaging and navigation, with augmented reality and inclusion of haptic and sensory capabilities providing more targeted treatment of tumour resection. The real challenge is in providing a cost-effective robotic platform to provide for the majority of patients.

Whereas the capability and results of the surgeon were previously based on cognition, vision, technique and dexterity the urologist of the future may be the manager of connectivity, creativity and supervisor of surgery by automated intelligence.

Key Messages

1. The innovation in this field has been rapid over the last century, and the current technologies could not have been predicted.
2. New robots, and new adjuncts to the robots will become more accessible, and more widespread.
3. Once WIT, parenchymal loss and pre-operative renal function have been optimized, then new targets of preventative measures may take over.

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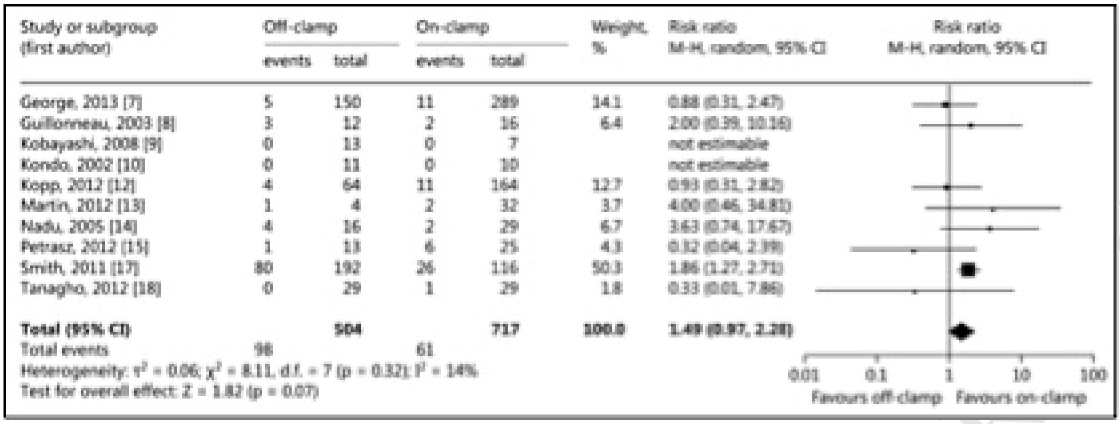
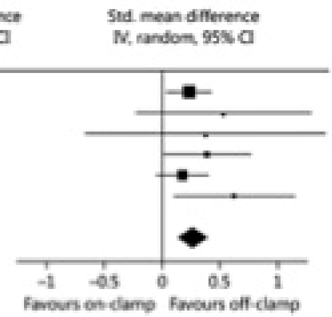
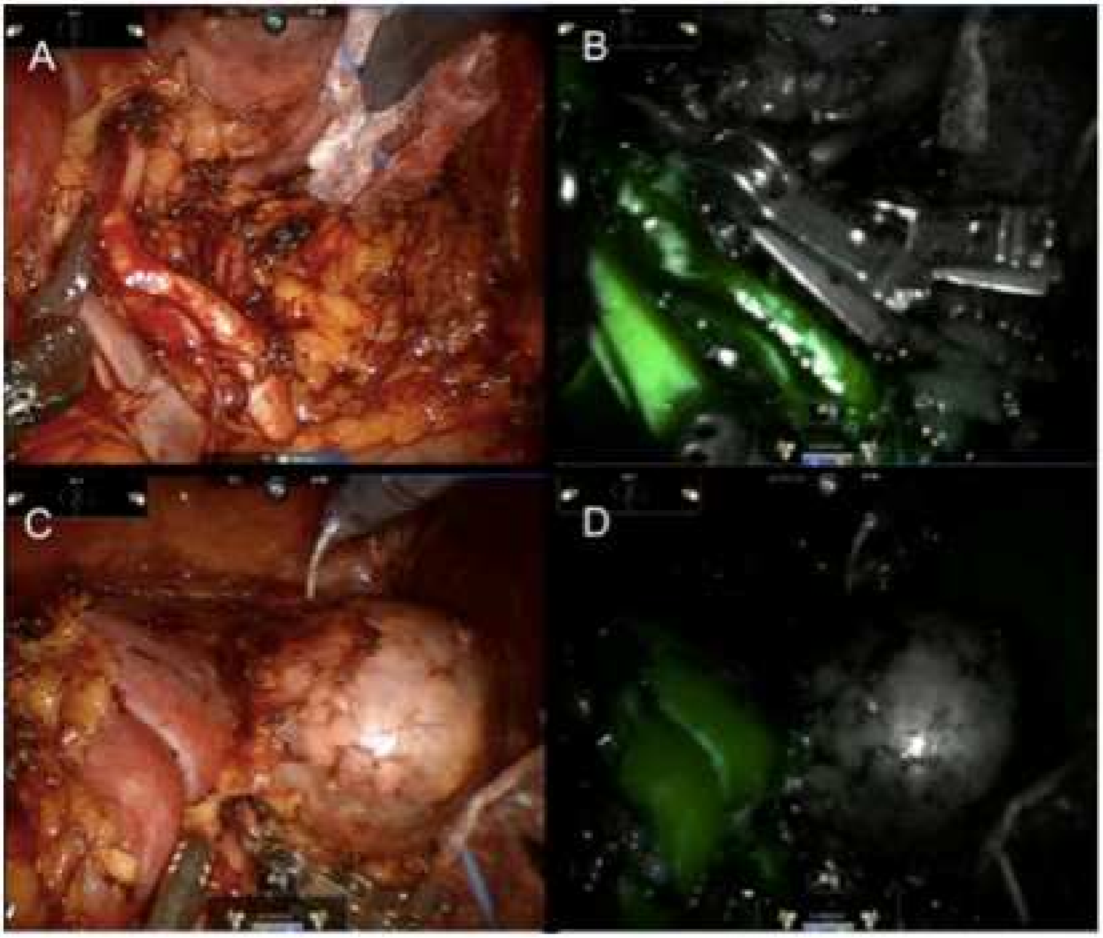

Study or subgroup (first author)
Off-clamp
On-clamp
events
total
events
total
Weight, %
Risk ratio M-H, random, 95% CI
Risk ratio M-H, random, 95% CI
George, 2013 [7] 5 150 11 289 14.1 0.88 (0.31, 2.47)
Guillonneau, 2003 [8] 3 12 2 16 6.4 2.00 (0.39, 10.16)
Kobayashi, 2008 [9] 0 13 0 7 not estimable
Kondo, 2002 [10] 0 11 0 10 not estimable
Kopp, 2012 [12] 4 64 11 164 12.7 0.93 (0.31, 2.82)
Martin, 2012 [13] 1 4 2 32 3.7 4.00 (0.46, 34.81)
Nadu, 2005 [14] 4 16 2 29 6.7 3.63 (0.74, 17.67)
Petrasz, 2012 [15] 1 13 6 25 4.3 0.32 (0.04, 2.39)
Smith, 2011 [17] 80 192 26 116 50.3 1.86 (1.27, 2.71)
Tanagho, 2012 [18] 0 29 1 29 1.8 0.33 (0.01, 7.86)
Total (95% CI) 504 717 100.0 1.49 (0.97, 2.28)
Total events 98 61
Heterogeneity: τ² = 0.06; χ² = 8.11, d.f. = 7 (p = 0.32); I² = 14%
Test for overall effect: Z = 1.82 (p = 0.07)
0.01
0.1
1
10
100
Favours off-clamp
Favours on-clamp

Study or subgroup (first author)	Off-clamp			On-clamp			Weight, %	Std. mean difference IV, random, 95% CI
	mean	SD	total	mean	SD	total		
George, 2013 [7]	−3.9	43.6	150	−11.7	26.2	289	44.6	0.23 (0.04, 0.43)
Guillonneau, 2003 [8]	−0.09	0.13	12	−0.2	0.24	16	3.0	0.53 (−0.23, 1.29)
Martin, 2012 [13]	−2.5	5.8	4	−6.8	11.6	32	1.6	0.38 (−0.67, 1.42)
Porpiglia, 2012 [16]	−0.17	9.3	41	−4.38	11.37	76	11.9	0.39 (0.01, 0.77)
Smith, 2011 [17]	−9.8	15	116	−12.3	14	190	32.6	0.17 (−0.06, 0.40)
Tanagho, 2012 [18]	−4.9	8.9	29	−11.7	12.3	29	6.3	0.62 (0.10, 1.15)
Total (95% CI)			**352**			**632**	**100.0**	**0.27 (0.14, 0.40)**

Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 3.40$, d.f. = 5 ($p = 0.64$); $I^2 = 0\%$

Test for overall effect: $Z = 3.99$ ($p < 0.0001$)

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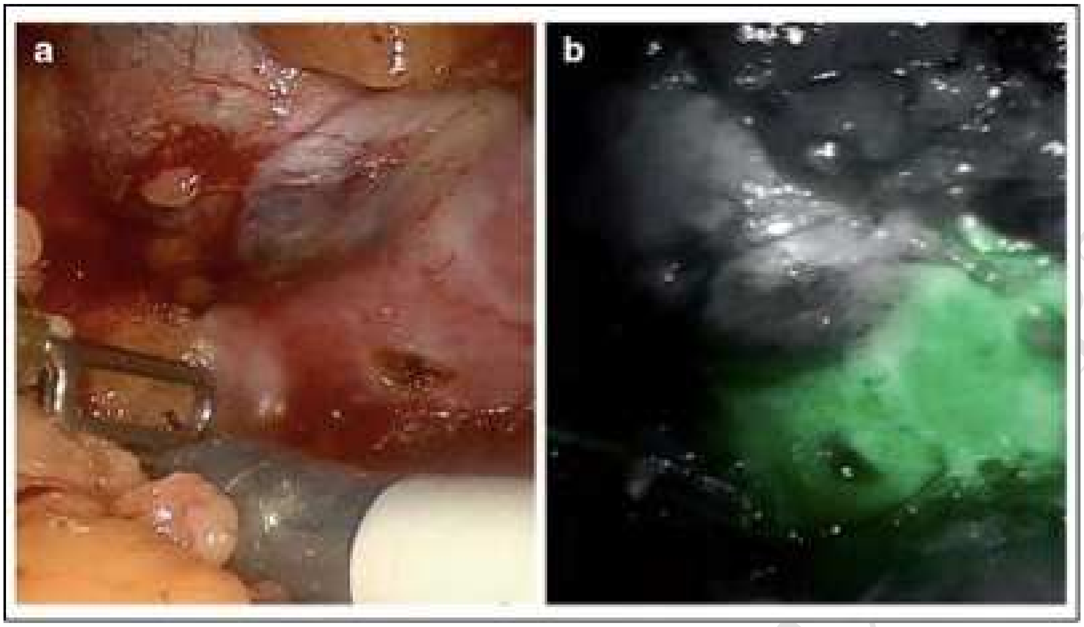
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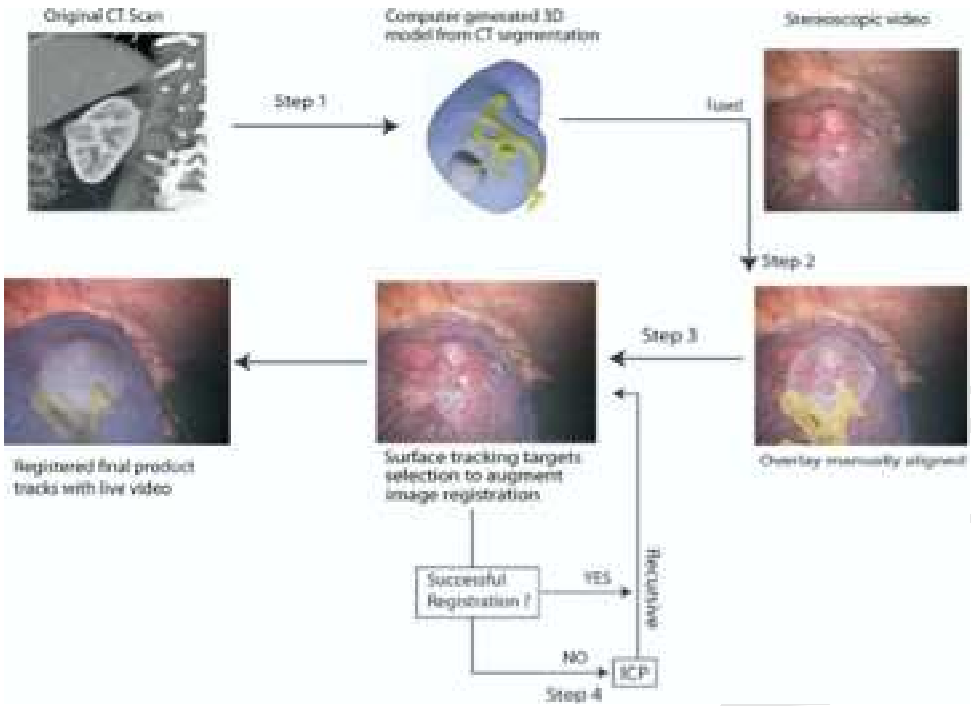
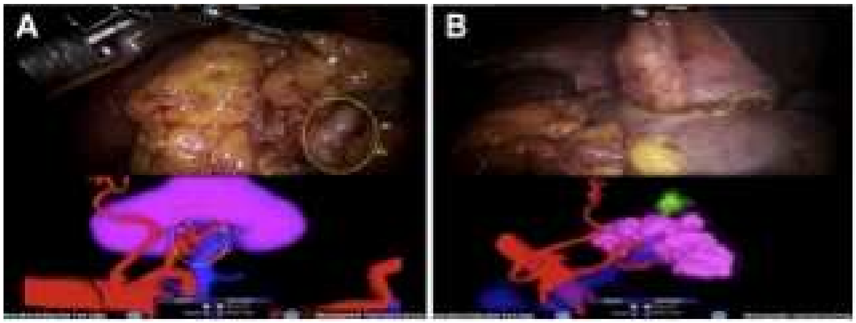


Original CT Scan
Computer generated 3D model from CT segmentation
Stereoscopic video
Step 1
Fused
Step 2
Step 3
Overlay manually aligned
Registered final product tracks with live video
Surface tracking targets selection to augment image registration
Successful Registration ?
YES
NO
ICP
Step 4
Recursive


A
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SurgiCal
ROBOTICS

Highlights

1. The innovation in this field has been rapid over the last century, and the current technologies could not have been predicted.
2. New robots, and new adjuncts to the robots will become more accessible, and more widespread.
3. Once WIT, parenchymal loss and pre-operative renal function have been optimized, then new targets of preventative measures may take over.